

REMARKS

I. INTRODUCTION

Favorable reconsideration of this application, in light of the present amendments and following discussion, is respectfully requested.

II. STATUS OF THE CLAIMS

Claims 1-54 are pending; Claims 1-14, 19, 25, and 27-33 are amended; Claims 40-54 are newly added; and no claims are cancelled herewith. It is respectfully submitted that no new matter is added by this amendment.

III. SUMMARY OF THE OFFICE ACTION

In the outstanding Office Action, Claims 25-35 were rejected under 35 U.S.C. § 102(b) as anticipated by *Silverstone* (U.S. Patent No. 6,161,044). Additionally, Claims 37-39 were rejected under 35 U.S.C. § 103 as obvious over *Silverstone*. Claims 1-15, 17-21, 23, and 24 were also rejected under 35 U.S.C. § 103 as unpatentable over *Silverstone* in view of *Pless* (U.S. Patent Pub. No. 2002/0169485). Claims 16, 22, and 36 were indicated as allowable.

IV. ALLOWABLE SUBJECT MATTER

Applicants acknowledge with appreciation the indication that Claims 16, 22, and 36 contain allowable subject matter. Newly added Claims 40-42 represent the subject matter of these claims in independent form. Accordingly, it is respectfully submitted that Claims 40-42 are in condition for allowance and that no new matter has been added by Claims 40-42.

V. REJECTION UNDER 35 U.S.C. § 102(b)

In the outstanding Office Action, Claims 25-35 were rejected under 35 U.S.C. § 102(b) as anticipated by *Silverstone*. For the reasons discussed below, this rejection is respectfully traversed.

As amended, Claim 25 recites, in part, “positioning at least two pairs of surface electrodes at predetermined peripheral surface stimulation sites on the subject’s skin surface based at least in part on a neural image”¹ Claims 27 and 33 recite analogous features, and Claims 26, 28-32, 34, and 35 depend from Claims 25, 27, and 33, respectively.

As described in the specification (for example) at page 6, dermatome maps and PET scans provide a visual indication of effective areas of treatment for the brain. According to an aspect of the present invention, the dermatome maps and PET scans enable a determination of the optimum location of treatment to minimize essential tremor.

Silverstone is directed to treatments using high frequency, high intensity transcutaneous electrical nerve stimulation. However, *Silverstone* does not disclose or suggest using a neural image to position electrodes at predetermined stimulation sites. In fact, *Silverstone* does not in any way address the benefits or potential advantages of using neural images because *Silverstone* does not describe any type of neural image as a part of the treatment method. As a result, *Silverstone* necessarily fails to disclose or suggest “positioning at least two pairs of surface electrodes at predetermined peripheral surface stimulation sites on the subject’s skin surface based at least in part on a neural image ...” as recited in independent Claims 25, 27, and 33.

Therefore, as *Silverstone* fails to disclose or suggest the features of independent Claims 25, 27, and 33, it is respectfully requested that the rejection of these claims be withdrawn. Likewise, it is respectfully requested that the rejection of dependent Claims 26, 28-32, 34, and 35 be withdrawn.

¹ Support for this amendment may be found in the specification at page 6, for example. Accordingly, it is respectfully submitted that no new matter is added by this amendment.

VI. REJECTIONS UNDER 35 U.S.C. § 103

A. *Silverstone*

Claims 37-39 were rejected under 35 U.S.C. § 103 as obvious over *Silverstone*. For the reasons discussed below, this rejection is respectfully traversed.

Claims 37-39 depend from Claim 33. As noted above, *Silverstone* does not disclose or suggest using any type of neural image. Accordingly, it is respectfully requested that the rejection of Claims 37-39 be withdrawn.

Additionally, it appears that the outstanding Office Action has taken Official Notice that certain claimed features (e.g., the method steps of Claims 37-39) are obvious over *Silverstone*. However, no references are cited to support the assertions that the claimed steps are obvious.

As set forth in MPEP § 2144.03, it is not appropriate to take Official Notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well known. Moreover, it is never appropriate to rely on “common knowledge” in the art without evidentiary support in the record as the principal evidence upon which a rejection is based. *In re Zurko*, 258 F.3d 1379, 1381 (Fed. Cir. 2001).

In this case, there is no evidence in the record to support the allegations of obviousness at pages 2-3 of the outstanding Office Action. Accordingly, as the Office Action has not satisfied the requirements of MPEP § 2144.03, it is respectfully submitted that the outstanding Office Action has not provided a *prima facie* case of obviousness with respect to Claims 37-39. It is therefore respectfully requested that this rejection be withdrawn.

B. *Silverstone* in view of *Pless*

Additionally, Claims 1-15, 17-21, 23, and 24 were rejected under 35 U.S.C. § 103 as unpatentable over *Silverstone* in view of *Pless*. This rejection is respectfully traversed.

Independent Claims 1, 7, 13, and 19, from which Claims 2-6, 8-12, 14-18, and 20-25 respectively depend, all recite the use of a neural image. As noted above, *Silverstone* does not disclose or suggest this feature. Because *Pless* is not relied upon to provide this feature identified as deficient in *Silverstone*, *Pless* is not substantively addressed herewith.

Therefore, Claims 1-15, 17-21, 23, and 24 patentably distinguish over the applied combination of *Silverstone* and *Pless*, and it is respectfully requested that this rejection be withdrawn.

Moreover, it is respectfully submitted that there is no basis in the teachings of either *Silverstone* or *Pless* to support the applied combination. Certainly, the outstanding Office Action fails to cite to any specific teachings in either reference to support the applied combination. Thus, the only apparent motivation for the combination must be the teachings of the present specification. Accordingly, it is respectfully submitted that the combination of *Silverstone* with *Pless* is the result of hindsight reconstruction in view of the teachings of the present specification, which is improper.

Additionally, it appears that the Office Action has taken Official Notice that a field programmable gate array would have been obvious to one of ordinary skill in the art. *Office Action*, page 3. The Office Action further states that using a sine wave would have been obvious “since such has been shown to have wide applicability in treating patients, to modulate neural activity.” *Office Action*, page 3. The Office Action further alleges, without explanation, that the circuitry of Figure 5 of *Pless* is “analogous to the digital signal processor

called for in the claims.” *Office Action*, page 3. However, no references are cited in support of any of these assertions.

As explained above, and as set forth in MPEP § 2144.03, it is not appropriate to take Official Notice of facts without citing a prior art reference where the facts asserted to be well known are not capable of instant and unquestionable demonstration as being well known. Certainly, it is never appropriate to rely on “common knowledge” in the art without evidentiary support in the record as the principal evidence upon which a rejection is based. *In re Zurko*, 258 F.3d 1379, 1381 (Fed. Cir. 2001).

It is respectfully noted that the outstanding Office Action has not cited any references to support the allegations of obviousness at page 3 of the Office Action. As a result, the outstanding Office Action has not provided a *prima facie* case of obviousness, because the requirements set forth in MPEP § 2144.03 have not been satisfied. It is therefore respectfully requested that the rejection of Claims 1-15, 17-21, 23, and 24 be withdrawn.

VII. NEW CLAIMS


Newly added Claims 43-54 recite subject matter previously disclosed in the specification, for example, at pages 3-4. Accordingly, it is respectfully submitted that new Claims 43-54 do not add any new matter. Claims 43-54 depend, respectively, from Claims 1, 7, 13, 19, 27, and 33. As discussed above, these claims are believed to patentably distinguish over the references of record. Claims 43-54 are likewise believed to patentably distinguish over the references of record for at least the reasons above-noted with regard to the independent claims from which they depend.

VIII. CONCLUSION

Consequently, in view of the foregoing discussion and present amendments, it is respectfully submitted that this application is in condition for allowance. An early and favorable action is therefore respectfully requested.

Respectfully submitted,

BLANK ROME LLP

By: 
Michael C. Greenbaum
Reg. No. 28,419

600 New Hampshire Ave., N.W.
Washington, D.C. 20037
Telephone: (202) 944-3000
Atty. Docket No.: 000309-00032
Date: May 3, 2006
MCG/KPB/rc

Katherine P. Barecchia
Registration No. 30,607